

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0673574	(X3) Date Survey Completed 06/17/2020
Name of Provider or Supplier Northeast Florida Endocrine & Diabetes Assoc	Street Address, City, State 3550 University Blvd South Suite 301, Jacksonville, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	At the time of the announced, onsite recertification survey, Northeast Florida Endocrine & Diabetes Associates was found to not in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation and staff interview, the facility failed to ensure the pipette used for making chemistry quality control had been checked for adequate and consistent delivery since 5/26/2017. The findings include: During the tour of the laboratory on 6/17/20, the Finnpipette Fixed 3ml pipette was observed hanging off the Vitros250 (Chemistry analyzer) with the last calibration check having occurred on 5/26/17. The pipette has been overdue for calibration since 5/26/2018. The interview with the laboratory Technical Consultant on 6/17/20 at 10:30am confirmed the pipette was overdue for calibration.</p>